K131862

SUN NUCLEAR corporation

Your Most Valuable QA & Dosimetry Tools

Section 6 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

June 21, 2013

Submitted by:

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AUG 2 1 2013

Contact Person:

Jeff Kapatoes
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Classification Name:

Accelerator, Linear, Medical

Common Name:

Dosimetric Quality Assurance for Patient Specific Radiation Treatment

Proprietary Names:

Model 1212 3DVH

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Product code: IYE

Predicate Device:

Model Name:	Compass
Common Name:	Accelerator, linear, medical
510(k) #	K072374
Manufacturer:	Scanditronix Wellhdfer GmbH
Cleared:	Dec 7, 2007

2 Description:

The Sun Nuclear 3DVH product, model 1212, is a software application that creates an estimated patient dose distribution using data measured during delivery of the treatment plan to certain 2D or 3D detector arrays and the planning patient dose volume computed by the treatment planning system (TPS) as inputs. The patented 3DVH dose algorithm (US patent #7,945,022) uses the measured data to make perturbations to the TPS patient dose volume to produce the estimated patient dose volume. From a comparison of the 3DVH result to the TPS planned dose, a qualified clinician makes the decision whether the TDD along with its accessories (including the treatment planning system, or TPS) is capable of delivering the treatment as prescribed.

3 Intended Use Statement:

Sun Nuclear Corporation (SNC) Model 1212 3DVH has the following intended use:

> Model 1212 3DVH is a radiotherapy dose delivery quality assurance (QA) software application intended to estimate the dosimetric impacts of the deviations and imperfections of a treatment delivery device, and its accessories, on the 3D patient dose volume as defined by a treatment planning system (TPS). These dosimetric impacts are based upon QA measurement of the radiation dose distributions that are delivered to a phantom.

While the exact wording of this Intended Use and that for the predicate are not identical, the intended uses are substantively the same with one exception: Compass claims input from "online or offline measurements". "Online" use implies with the patient present during patient treatment. Model 3DVH is only intended with input from "offline" measurements, i.e without the patient present. This difference is not critical to the intended diagnostic use of the device since 3DVH is intended for quality assurance performed without the patient present, typically done before treatment commences. The difference does not affect the safety and effectiveness of the device when used as labeled because 3DVH is only intended to be used with input acquired offline. Use of online measurements would constitute a different intended use and thus a different product.

4 Technological Characteristics

Model 1212 3DVH shares both similar and different technological characteristics. Similar characteristics include the use DICOM input data from third party treatments systems and analysis tools such as dose volume histogram (DVH) display, color-wash dose display for multiple anatomical planes, and structure-based dose statistics. A different technological characteristic is the algorithm used to produce the estimated patient dose volume.

5 Performance Data

3DVH has been tested in non-clinical and clinical settings, and it has been shown that this device performs within its design specifications and industry-specific guidelines. Performance testing included extensive benchmarking of the dose calculation algorithm (its individual components and as an integrated whole). Performance testing also included confirmation of the computed dose volume histogram data and comparison tools such as dose different, distance-to-agreement, and gamma index analysis. Based on the results of this performance testing, Model 1212 3DVH is as safe, as effective, and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2013

Sun Nuclear Corporation
% Jeff Kapatoes, Ph.D.
Product Manager
3275 Suntree Blvd.
MELBOURNE FL 32940

Re: K131862
Trade/Device Name: Model 1212 3DVH
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 21, 2013
Received: June 27, 2013

Dear Dr. Kapatoes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

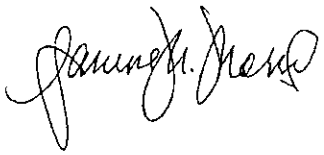
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131862

Device Name: Model 1212 3DVH

Indications for Use:

Intended Use:

Model 1212 3DVH is a radiotherapy dose delivery quality assurance (QA) software application intended to estimate the dosimetric impacts of the deviations and imperfections of a treatment delivery device, and its accessories, on the 3D patient dose volume as defined by a treatment planning system (TPS). These dosimetric impacts are based upon QA measurement of the radiation dose distributions that are delivered to a phantom.

Perscription Use ___X___ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K131862